UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

MEMORANDUM

DATE: January 25, 2011 JAN 2 5 2011

SUBJECT: Review of Registrant Response to Deficiency Letter in Support of the Registration of *Moss Buster*, Containing 1.0 % Oregano Oil (from *Origanum vulgar*) As Its Active Ingredient.

Decision Number:	**384851**
DP Number:	**385998**
EPA File Symbol Number:	**84316-R**
Chemical Class:	**Biochemical**
PC Code:	**004300**
CAS Number:	**8007-11-2**
Active Ingredient Tolerance Exemptions:	**Non-Food Use**
MRID Numbers:	**48322100-04**
Specific Type of Review:	**Product Chemistry, Toxicology (Human & Non-Target)**

FROM: *Sadaf Shaukat, Biologist*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: *Leonard Cole, Regulatory Action Leader*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to the request for additional information discussed in a memorandum from Sadaf Shaukat to Leonard Cole dated 10/26/10 and relayed in a letter from BPPD to the registrant dated 11/24/10, the registrant has submitted a letter dated 12/10/10 attempting to address all deficiencies, including revised product chemistry data (MRID's 48322101, -03, -04), and revised non-target toxicology data (MRID 48322102). This memorandum is a review of the registrant response to all cited deficiencies.

RECOMMENDATIONS AND CONCLUSIONS

1. The product chemistry submission is UNACCEPTABLE, but upgradeable pending resolution of deficiencies listed below.
MRID 48322101: UNACCEPTABLE
MRID 48322103: UNACCEPTABLE
MRID 48322104: ACCEPTABLE

a. The registrant must submit a revised CSF with the revised upper certified limit for the active ingredient (based on values obtained in the preliminary analysis).

b. Physical and chemical characteristics were submitted for the TGAI, however one requirement was missing. The registrant must submit information to address OCSPP 830.7050-UV/Visible Absorption.

NOTE TO RAL:

a. Quality control methods/techniques must be provided for the production and formulation process of the EP. (OCSPP Guideline 880.1200). *The Agency has allowed the registrant 12 months after registration to submit this guideline study.*

b. The following components of the preliminary analysis are missing and *must be provided by the registrant at a later date, to be determined by the RAL* (see EPA Product Properties Test Guideline: OCSPP 830.1700):

1. Summary and Introduction: Scope and Source of Method
2. Materials and Methods: Equipment, Reagents and Standards, Detailed Analytical Procedure
3. Results and Discussion: Accuracy and Precision, Limits of Detection and Quantification
4. Conclusions: Applicability of Analytical Procedure

c. Results of one-year storage stability and corrosion characteristics studies must be submitted for the EP *12 months after registration.* (OCSPP 830.6317, 830.6320)

2. **The human toxicology submission is ACCEPTABLE to satisfy all Tier 1 human health data requirements.**

3. **The non-target toxicology submission is UNACCEPTABLE to satisfy all Tier 1 non-target requirements. The deficiencies listed below must be adequately addressed in order to upgrade to *acceptable*.**
MRID 48322102: UNACCEPTABLE

Studies and/or scientifically-credible rationale were **not** submitted to support the following Tier I data requirements (40 CFR 158.2060). These requirements must be addressed:

Seedling Emergence (OCSPP Guideline 850.4100)
Vegetative Vigor (OCSPP Guideline 850.4150)
Nontarget Insect Testing-Honeybee acute contact toxicity (OCSPP Guideline 850.3020)

a. Insufficient rationale was provided to fulfill the requirements for **seedling emergence** and **vegetative vigor (OCSPP 850.4100/4150).** The Agency requested that the registrant submit scientifically-valid reference/citation to support the claim that Moss Buster is a selective herbicide. In the registrant response, it is indicated that there may be transient adverse effects to non-target plants. The registrant refers to unpublished studies that would provide more details. The registrant must explain what this "transient adverse" effect is and submit this unpublished data in order for the Agency to properly assess risk to non-target plants. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

b. Insufficient information was provided to fulfill the data requirement for **non-target insect testing/honeybee acute contact toxicity (OCSPP 850.3020)**. The registrant provided a reference generated by USDA which lists insects that attack oregano leaves. This information is irrelevant, as the substance in question is concentrated oregano oil, and not oregano leaves. The registrant must provide information from the literature to substantiate the claim that oregano oil will not adversely affect non-target species, specifically the honey bee. Refer to this link for more information: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Drafts/850-3020.pdf

cc: *S. Shaukat, L. Cole*, BPPD Science Review File, IHAD/ARS
S. Shaukat, FT, PY-S: *1/25/10*